IN THE UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF NORTH CAROLINA

SYNGENTA CROP PROTECTION, LLC, Plaintiff, v. WILLOWOOD, LLC, WILLOWOOD USA, LLC, WILLOWOOD AZOXYSTROBIN, LLC, and WILLOWOOD LIMITED, Defendants.	Civil Action No: 1:15-CV-274

SYNGENTA'S RESPONSE TO THE STATEMENT OF INTEREST OF THE UNITED STATES

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Fundamentally, the government, just as Willowood does, asks this Court to cast aside the well-reasoned opinion in *FMC* and usurp the role of Congress to create what would be an unprecedented and unwarranted judge-made exception to copyright infringement for manufacturers of generic pesticides. *FMC Corp. v. Control Sols., Inc*., 369 F. Supp. 2d 539 (E.D. Pa. 2005) (holding pesticide labels are subject to copyright). "[W]here two statutes are 'capable of co-existence, it is the duty of the courts, absent a clearly expressed congressional intention to the contrary, to regard each as effective.'" *Ruckelshaus v. Monsanto Co.*, 467 U.S. 986, 1018 (1984). FIFRA does not conflict with the Copyright Act and, in fact, explicitly requires the EPA to accept and expedite review of applications for me-too products with labels that differ from the original products, so long as they do not significantly increase the risk of unreasonable adverse effects on the environment. 7 U.S.C. § 136a(c)(3)(B)(i)(I); *FMC*, 369 F. Supp. 2d at 558–71. For their part, neither the government nor Willowood presents any statutory basis or shred of legislative history to demonstrate that there is a conflict or that Congress intended FIFRA to preempt the Copyright Act. At most, the government asserts that FIFRA *allows* the use of identical or substantially similar me-too pesticide labels, assuming, of course, that the labels comport with any applicable intellectual property rights. But the government does not, and cannot, demonstrate that FIFRA *requires* identical or substantially similar labels.

Nor has the EPA imposed such a requirement. The government suggests that the EPA, at most, "encourages" me-too labels to be identical or substantially similar out of a concern that the EPA's resources will be tied up in reviewing dissimilar labels. But that is a policy concern that the EPA should properly address to Congress, not to this Court. Indeed, it has been over a decade since the court in *FMC* determined that pesticide labels are properly subject to copyright protection. Yet, the sky has not fallen over the EPA, and Congress has not intervened to amend FIFRA or the Copyright Act.

The government raises other arguments[1] that largely repeat the arguments that Willowood makes and that Syngenta addresses below. Ultimately, neither Willowood, nor the government, identifies any material issues of fact to preclude summary judgment in Syngenta's favor that (1) Willowood copied Syngenta's QUADRIS® and QUILT XCEL® labels; (2) Syngenta's labels are copyrightable; (3) FIFRA does not preclude Syngenta's copyright claims, and (4) Willowood's copying was not fair use. Therefore, this Court should maintain its preliminary ruling denying Willowood's Motion for Summary Judgment (Dkts. 87–89) and further grant summary judgment *sua sponte* in Syngenta's favor on these four issues, which are well developed on the record. *See Celotex Corp. v. Catrett*, 477 U.S. 317, 326 (1986) ("[D]istrict courts are widely acknowledged to possess the power to enter summary judgments *sua sponte*.").

I. FIFRA Does Not Preclude Syngenta's Copyright Claims.

A. Nothing in FIFRA or the EPA's Implementation of FIFRA Requires Blatant Copying of Pesticide Labels.

The government asserts FIFRA "authorizes" me-too applicants to use identical or substantially similar labels to that of the original registrant and that the EPA "prefers" or even "encourages" identical or substantially similar label language. (SOI at 2, 4, 8, 20, 24, 25, 36.) The government, however, does not, and cannot, demonstrate that FIFRA (or

[1] This Court may strike or decline to consider the government's Statement in its entirety because it is an unauthorized and untimely amicus brief that fails to comply with LR7.5 that the government filed long after Willowood's motion for summary judgment and without leave from this Court. *See United States v. North Carolina*, No. 1:13CV861, 2014 WL 494911, *5 (M.D.N.C. Feb. 6, 2014) (stating that a party should follow LR7.5 when filing an amicus brief). Moreover, Syngenta understands that Willowood's counsel originally contacted the government and had spoken multiple times with the government over the course of a couple of months leading up to the filing of the Statement. (Levine Decl. ¶ 2.) Yet, the first time Syngenta received any notice that the government might (or would) file the Statement was on February 27, 2017—shortly after this Court circulated its draft summary judgment order, a few hours before the government filed the Statement, and less than a day before the scheduled summary judgment hearing in this case. (*Id.* ¶ 3.)

the EPA through its regulations and practice) ***requires*** me-too applicants to use identical or substantially similar labels.[2] As the court in *FMC* expressly found, nothing in FIFRA, the applicable regulations, or the EPA Label Review Manual requires "verbatim or nearly wholesale copying of another registrant's label . . . to obtain expedited review by the EPA of a label." *FMC*, 369 F. Supp. at 560.

Indeed, FIFRA's plain language refutes any suggestion that it requires me-too applicants to engage in label copying. Specifically, FIFRA provides:

> The Administrator ***shall, as expeditiously as possible, review and act on any application*** received by the Administrator that . . .
>
> would be identical or substantially similar in composition and labeling to a currently-registered pesticide identified in the application, ***or***
>
> that would ***differ in*** composition and ***labeling*** from such currently-registered pesticide only in ways that would not significantly increase the risk of unreasonable adverse effects on the environment.

7 U.S.C. § 136a(c)(3)(B)(i)(I) (emphasis added). For its part, the government focuses on the first clause of this provision to make the unremarkable proposition that me-too products with "identical or substantially similar" labeling will receive expedited review by the EPA. (SOI at 8, 15.) But the government largely ignores the second clause that requires the EPA to accept and expeditiously review all me-too applications that ***differ in composition and labeling,*** provided that they "do not significantly increase the risk of unreasonable adverse effects to the environment."

Moreover, as in *FMC*, the EPA's "basic directions for label review . . . undermine [any] contention that near-verbatim copying is necessary to achieve expedited review for

[2] FIFRA does not use the words "authorize" or "permit," and the government's use of these words is misleading. To be sure, there may be some circumstances in which an identical or substantially similar label is submitted to the EPA, such as when an original registrant repackages its own product or when a me-too applicant obtains a license to use a copyrighted label. But FIFRA does not "authorize" or "permit" copyright infringement.

a me-too product." 369 F. Supp. 2d at 557. To be sure, as the government notes, the EPA's Label Review Manual instructs reviewers to make a "side-by-side" comparison of the proposed set of use directions for a me-too product and those of the original product. (SOI at 11.) But as the court in *FMC* recognized, this directive is not "designed to assure (and, thereby require) copying." 369 F. Supp. at 558. In fact, the Label Review Manual warns reviewers "against limiting themselves to label-to-label comparisons," *id.*, and specifically instructs reviewers "to use the guidance [provided in policy documents] along with applicable laws to make case-by-case determinations on the acceptability of label language" (Ex. 1, EPA Label Review Manual, Ch. 11 at 11-5 (Dec. 2014)). Nor is there any "reason to doubt that EPA personnel have the requisite education, skill and experience in their respective fields to determine . . . whether the language in purportedly similar labels has the same import." *FMC*, 369 F. Supp. at 558.

Further, the applicable regulations "provide significant latitude to determine the content and placement of product label language," and, for example, merely require that "'directions for use' . . . be drafted with plain language that is easily understood." *Id*. at 559 (citing 40 C.F.R. § 156.10). As the court in *FMC* recognized, the Label Review Manual and Pesticide Registration Notices have "advised registrants to develop their own language for product labels." *Id.* (citations omitted). In fact, for example, the EPA advises that "[s]pecific storage instructions ***are not*** prescribed" and that "[e]ach registrant must develop his own storage instructions." (Ex. 2, Pesticide Registration Notice 83-3 at 2 (1983) (emphasis added).) The Label Review Manual also recognizes that the directions for use on a product may be presented in different ways and provides:

> ***The format for the presentation of use information*** on the identical or substantially similar label ***need not be identical to the format on the registered (cited) label*** as long as the critical information as described above remains the same and the identical product meets applicable legal requirements on labeling.

(Ex. 1, Label Review Manual at 11-9 to 11-10; *see also FMC*, 369 F. Supp. at 559. Therefore, not only does FIFRA expressly require the EPA to accept and review me-too products with labels that differ from the original product, but also the EPA's regulations and policies provide considerable flexibility in developing such labels.[3]

B. The Government Does Not, and Cannot, Identify Any Actual Conflict Between FIFRA and the Copyright Act.

Just as Willowood does, the government essentially asks this Court to assume Congress' role and carve out a judge-made exception to copyright infringement for generic pesticide labels. "Where two statutes are 'capable of co-existence," however, it is the duty of the courts, absent a clearly expressed congressional intention to the contrary, to regard each as effective.'" *Ruckelshaus*, 467 U.S. at 1018. Neither the government, nor Willowood, identifies any statutory basis or legislative history to suggest that there is a conflict between FIFRA and the Copyright Act, much less that Congress intended FIFRA to preempt copyright protection. As discussed above, and as the court in *FMC* expressly found, no conflict exists because FIFRA does not require "verbatim or nearly wholesale copying of another registrant's label . . . to obtain expedited review by the EPA of a label." *FMC*, 369 F. Supp. at 560. To the contrary, FIFRA explicitly allows, and in fact requires, the EPA to accept me-too applications with labels that differ from those of the original registrant. 7 U.S.C. § 136a(c)(3)(B)(i)(I).

Nor is there any evidence of record that Congress intended generic pesticide labels to be excepted from copyright infringement. FIFRA, as it exists today, largely reflects the revisions that Congress enacted in 1972. 7 U.S.C. § 136 *et seq.*; Linda-Jo Schierow & Robert Esworth, *Pesticide Law: A Summary of the Statutes*, Report No. RL31921,

[3] The EPA requires certain language in pesticide labels, such as particular warnings. Syngenta does not claim copyright protection in these portions but rather the vast majority of its labels that the EPA does not specifically prescribe. (Dkt. 113 at 24.)

CONGRESSIONAL RESEARCH SERVICE 2–3 (Nov. 14 2012) ("Schierow"), *available at* http://www.law.umaryland.edu/marshall/crsreports/crsdocuments/RL31921_11142012.pdf. Four years later, Congress passed the Copyright Act of 1976, in a major overhaul of earlier copyright laws. 17 U.S.C. §§ 101–810, 1001–201; *Copyright Law of the United States and Related Laws Contained in Title 17 of the United States Code*, Circular 92, U.S. COPYRIGHT OFFICE i (Dec. 2016) ("UCO Circular"), *available at* https://www.copyright.gov/title17/title17.pdf. Congress, however, did not at that time, or in any later amendments to FIFRA or the Copyright Act, see fit to create the exception that the government and Willowood propose. In fact, since the *FMC* decision in 2005, Congress has amended FIFRA at least once and the Copyright Act at least eleven times. Schierow at 4 (listing 1 amendment); UCO Circular at xi–xii (listing 11 amendments). If anything, Congress' clear directive in FIFRA that the EPA must accept and review products with dissimilar labels combined with its silence as to the *FMC* decision reflects Congress' acceptance of *FMC* and underscores the lack of any conflict.

Moreover, where Congress sought to modify existing intellectual property law rights through FIFRA, it did so directly and explicitly. For example, Congress recognized that original registrants who conduct scientific studies to generate and submit data to the EPA in support of a pesticide registration have a property interest in that data that may be cognizable under certain state laws. *Ruckelshaus*, 467 U.S. at 1002–03. In 1978, Congress amended FIFRA to add data exclusivity and data compensation provisions that specifically limited these state-law rights and effectively put in place a forced licensing scheme that allows generics to rely on (but not to view) the original registrant's health and safety data to support a me-too registration in exchange for providing data compensation to the original registrant. *Id.* at 1006–08. *See id.*; 7 U.S.C. § 136a(c)(1)(F). Yet, Congress did not enact then, nor has it enacted since, any

provisions purporting to limit other existing intellectual property rights held by pesticide registrants under established law, including any copyright, patent, or trademark rights.

C. The Court in *FMC* Correctly Found *SmithKline* Inapplicable to Pesticide Labels Governed by FIFRA.

The government's arguments based on *SmithKline* are unavailing. (SOI at 16–21 (discussing *SmithKline Beecham Consumer Healthcare L.P. v. Watson Pharms., Inc.*, 211 F.3d 21 (2d Cir. 2000).) Specifically, in *SmithKline*, the court found that a drug label regulated by the Food and Drug Administration (FDA) was not copyrightable because (a) the Hatch-Waxman Amendments "required near-verbatim copying" of branded labels by generic manufacturers, and thus, conflicted with the Copyright Act, and (b) the FDA had indicated "in no uncertain terms" that the defendant's product would not be approved unless the label language was "nearly identical, except for a name change." *FMC*, 369 F. Supp. 2d at 569-70 (discussing *SmithKline*, 211 F.3d at 22–23, 27–28). Because no similar conflict exists between FIFRA and the Copyright Act, and because FIFRA explicitly requires the EPA to accept and review dissimilar labels, the court in *FMC* correctly distinguished *SmithKline* and found it inapplicable to pesticide labels. *Id.*

Curiously, the government asserts that in distinguishing *SmithKline*, the court in *FMC* "failed to acknowledge that the 'me too' standard essentially requires the generic applicant to provide labeling that falls within the 'substantial similarity' test of copyright infringement." (SOI at 22.) As discussed in Section I.D, the government's "substantial similarity" argument misapprehends the nature of copyright protection. The government also incorrectly assumes that FIFRA ***requires*** me-too labels to be substantially similar to those of the original products. To the contrary, as set forth in the chart below, the Hatch-Waxman provision at issue in *SmithKline* places the *burden on the generic applicant* and expressly requires the use of the ***same labeling*** to obtain expedited FDA review, whereas

the relevant provision of FIFRA places the *burden on the EPA* and expressly requires the EPA to accept and expedite review of me-too applications that ***differ in labeling***:

Hatch-Waxman	FIFRA
"An abbreviated application for a new drug ***shall*** . . . show that the ***labeling proposed for the new drug is the same as the labeling approved for the listed drug*** . . . ." 21 U.S.C. § 355(j)(2)(A)(v) (emphasis added).	"The Administrator ***shall, as expeditiously as possible, review and act on any application*** received by the Administrator . . . that would ***differ in*** composition and ***labeling*** from such currently-registered pesticide only in ways that would not significantly increase the risk of unreasonable adverse effects on the environment." 7 U.S.C. § 136a(c)(3)(B)(i)(I) (emphasis added).

To be sure, the court in *SmithKline* found that "'same' may be something less than 'identical'" in the Hatch-Waxman context, but the court explained that "whatever difference may exist . . . is narrow and intended to prevent misstatements" such as allowing a generic manufacturer to change references in the label to the name/address of the manufacturer or the color of a product. 211 F.3d at 28 (citing H. Rep. No. 98-857, Part I at 22 (1984)). Thus, contrary to the government's suggestion (SOI at 19), Hatch-Waxman's "same" standard provides hardly any flexibility and does not remotely compare to the relatively wide latitude that FIFRA provides me-too applicants in developing differing labels. *FMC*, 369 F. Supp. at 558–60.

Moreover, unlike in *SmithKline*, Willowood has not presented any evidence that the EPA refused to approve its products absent copying of Syngenta's labels. To the contrary, as the court in *FMC* recognized, the EPA has expedited and approved me-too labels that have not been copied from an original registrant. 369 F. Supp. 2d at 552. Underscoring FIFRA's flexibility, the EPA indicates that of the "thousands" of me-too products it has registered, at least some have dissimilar labels. (SOI at 11.)

Citing *SmithKline*, the government further incorrectly asserts that denying copyright protection of pesticide labels will not undermine the purpose of copyright law because the "profit sought by [Syngenta] of the pioneer drug label flows primarily from the administrative approval of the drug and the patent and exclusivity periods free from competition that follow." (SOI at 19.) But unlike drug labels, for which Hatch-Waxman does not allow any creative room for companies to distinguish themselves, FIFRA's flexibility permits exactly that. Indeed, there are a multitude of ways in which a pesticide label may be drafted, some more clear, elegant, and user friendly than others in ways that can create a marketing advantage. For example, Syngenta's labels were drafted by technical asset managers in Syngenta's marketing group. (Dkt. 110-13, Clark Decl. ¶ 5; Dkt. 126-6.) As Dr. Adora Clark explained, Syngenta's labels were written with the grower in mind, and they tell Syngenta's "story" regarding how growers can use Syngenta's products to enhance yields and succeed in their business:

> [I]t's extremely important to create that right story for the grower because they have to be able to follow this in order to apply it and to be in compliance. It's not just for compliance reasons. It's for making [the product] work. I mean, let's face it, the grower wants to increase yields at the end of the day, so you've got to have that story for them, and we have a good reputation with the grower because we do try to make our tools with the full details so that they can have a higher yield. . . . You're putting it in a way that the grower can understand this and follow it and in a part of the label where you know they're going to look first. So it's just completely, you know, for the grower.

(Dkt. 125-2, Clark Tr. at 38:6-10, 45:15-24; 46:22-47:1; *see also id.* at 38:21-24, 179:3-21 (explaining labels are created in part with profit intent); Dkt. 110-13, Clark Decl. ¶ 2.)

D. The Government's "Substantial Similarity" Argument Misapprehends Copyright Law and Ignores that Willowood Has Conceded Copying.

The government erroneously argues that Syngenta's copyright infringement claims should be dismissed because "any 'me too' labeling, including Willowood's, is likely to infringe under th[e] 'substantial similarity' test" of copyright infringement. (SOI at 15;

see also id. at 18.) To establish copyright infringement, a plaintiff copyright holder must show that (1) it owns a valid copyright; and (2) the defendant copied the original elements of that copyright. *Bouchat v. Baltimore Ravens, Inc.*, 241 F.3d 350, 354–55 (4th Cir. 2000). When there is no direct evidence of copying, the plaintiff may raise a rebuttable presumption of copying by presenting evidence that "alleged copier had access to the material and that the original material and the alleged copy are substantially similar." *Keeler Brass Co. v. Cont'l Brass Co.*, 862 F.2d 1063, 1065 (4th Cir. 1988).

Here, Syngenta does not rely on circumstantial evidence of substantial similarity because Syngenta has direct evidence that Willowood purposefully copied Syngenta's labels. In particular, Brian Heinze, W-USA's CEO and Willowood's Rule 30(b)(6) designee on the creation of Willowood's labels, unequivocally testified that Willowood's initial Azoxy 2SC and AzoxyProp Xtra labels were copied from Syngenta's QUADRIS® and QUILT XCEL® labels. (Dkt. 110-1, Heinze Tr. Suppl. at 315:8–316:10.) Indeed, the initial Azoxy 2SC label that Willowood submitted to the EPA did not even replace all references to "Syngenta" with "Willowood." (Dkt. 1, Complaint ¶ 82; Dkt. 1-25 at 5.) Thus, copying is not an issue in this case, and given that the government concedes that it does not challenge the copyrightability of pesticide labels in general (SOI at 13), it is unclear how the government's argument is germane to Syngenta's copyright claims.

The government's argument also reflects a fundamental misunderstanding of the nature of copyright protection. Contrary to the government's suggestion, copyright law does not preclude generic manufacturers from using substantially similar labels, so long as those labels are not copied. *Selle v. Gibb*, 741 F.2d 896, 901 (7th Cir. 1984) ("[N]o matter how similar the two works may be (even to the point of identity), if the defendant did not copy the accused work, there is no infringement."). Indeed, to the extent that the question of substantial similarity even arises in a case, it can only create a *rebuttable*

presumption of copying, which a generic manufacturer could rebut by showing that it *independently* created its own label. *Keeler*, 862 F.2d at 1065. Willowood, however, does not, and cannot, claim that it independently created its labels.

Further, the government's argument improperly conflates the question of substantial similarity in the copyright context with that under FIFRA. Significantly, as the government appears to acknowledge, the question of whether two labels are substantially similar under FIFRA is a *substantive* one that is evaluated based on FIFRA's core registration requirement that a product not present a risk of "unreasonable adverse effects on the environment." (SOI at 10, 19 n.19); *see also* 7 U.S.C. §§ 136(bb) (defining "unreasonable adverse effects"), 136a(c)(3)(B)(i)(I), 136a(c)(5), 136a(c)(7)(A), 136a(c)(7)(B), 136a(c)(7)(C) (incorporating "unreasonable adverse effects" standard). Thus, pesticide labels can be substantially similar under FIFRA even though they differ in their selection, arrangement, and presentation of information such that they would not be substantially similar under copyright law. *See, e.g.*, *NTE, LLC v. Kenny Constr. Co.*, No. 14-cv-9558, 2016 WL 1623290, at *6 (N.D. Ill. Apr. 25, 2016) (finding no infringement where evidence did not establish copying of selection and arrangement).

E. The Government Provides No Support for the EPA's Alleged Practices and Policies, Which Ultimately Cannot Trump Copyright Protection.

The government proffers its Statement in an effort to counter *FMC*, stating that "there was no evidence from or on behalf of the EPA [in *FMC*] to advance the notion that the EPA ***requires*** generic or me-too applicants to copy the label language from the pioneer pesticide product." (SOI at 21–22 (emphasis added).) Yet, the government provides no such evidence to advance that notion here. Instead, just as Willowood does, the government relies heavily on tenuous policy rationales and unsupported assertions regarding alleged EPA practices that amount to little more than attorney argument.

For example, the government suggests the EPA "encourages the use of 'me too' label language that is identical or substantially similar to already registered pesticide label language." (SOI at 10; *see also id.* at 16.) But the government does not identify ***any*** written policy to that effect. To the contrary, as discussed in Section I.A, the applicable regulations and written policy documents provide wide discretion for drafting me-too labels, including as to the language and formatting, and specifically instruct EPA reviewers to evaluate labels on a case-by-case basis. Moreover, even if the EPA has an undocumented practice of *encouraging* identical or substantially similar me-too labels, that still does not evidence a policy ***requiring*** the submission of only such labels.

Similarly, the government does not present any declarations by any current EPA officials and simply asserts by way of attorney argument that it believes that the declarations of Lois Rossi (Dkt. 88-8) and Debra Edwards (Dkt. 88-9)—which were prepared and submitted a decade ago in other cases—"accurately reflected, and ***for the most part,*** still accurately reflect EPA practices with regard to 'me too' applications." (SOI 14 n. 14 (emphasis added).) Thus, the government concedes that the declarations do ***not*** entirely reflect current EPA practices. It is unclear, however, which parts of the EPA's current practices that they accurately reflect, which parts they do not, and what the government's support is. Nor does Syngenta have any ability to probe the statements in the Rossi and Edwards declarations, given Willowood's untimely disclosure of the declarations long after the close of fact discovery. Thus, for the reasons outlined in Syngenta's motion to exclude (Dkts. 107, 125), this Court should maintain its preliminary ruling excluding the Rossi and Edwards declarations.

This Court should also exclude Exhibit 11 attached to the government's Statement, which is an August 3, 2005 letter from Susan B. Hazen, another former EPA official. (Dkt. 132-11.) Similar to the Rossi and Edwards declarations, the government offers this

letter, which is not an official EPA policy document, as purportedly non-hearsay evidence for the truth of the matters contained in the letter concerning the EPA's position on the application of copyright protection to pesticide labels. Yet, like Ms. Rossi and Ms. Edwards, Ms. Hazen was never disclosed to Syngenta as a fact witness in Willowood's Rule 26(a) disclosures. Given that her first disclosure was in this letter attached to the government's statement of interest—more than half a year after fact discovery closed in this case—Syngenta did not have any ability to seek third-party discovery from Ms. Hazen concerning her statements in this letter. Further, like the Rossi and Edwards declarations, Ms. Hazen's letter proffers improper legal opinions, arguing that *FMC* was wrongly decided and advancing policy rationales for why pesticide labels, such as Syngenta's, should not be copyrightable. As Syngenta has previously highlighted to this Court, an expert may not opine on "what the law should be." *Norris v. Excel Indus., Inc.*, 139 F. Supp. 3d 742, 750 (W.D. Va. 2015). Thus, for the same reasons outlined in Syngenta's motion to exclude the Rossi and Edwards declarations (Dkts. 107, 125) and for the same reasons this Court preliminarily excluded those declarations, this Court should also exclude Ms. Hazen's August 3, 2005 letter.

Ultimately, the government's arguments that the EPA encourages (though does not require) substantially similar labels boils down to an unfounded policy concern that if this Court upholds Syngenta's copyright claims, the EPA will be overburdened by having to review numerous dissimilar me-too labels. (*See* SOI at 22.) The court in *FMC*, however, already held *over a decade ago* that regulated pesticide labels are copyrightable and can form the basis of copyright infringement actions. *See FMC*, 369 F. Supp. 2d at 568, 584. Yet, there is no indication that the *FMC* decision has caused the EPA's operations to come to a grinding halt. To the contrary, the government claims that the EPA has successfully reviewed "thousands of 'me too' products and [that] most of their

labels largely use language that is identical or substantially similar."[4] (SOI at 11.) And according to the EPA, there have only been five instances since *FMC* in which it has encountered copyright claims based on pesticide labels. (*Id.* at 13–14.) Thus, if the past is any indication, there is no reason to suggest that permitting Syngenta's copyright infringement claims will inundate the EPA with dissimilar me-too labels.

If anything, the EPA's concern is not with Syngenta's copyright claims but with FIFRA, which explicitly places the burden on the EPA to accept and review differing me-too labels and determine whether any differences would significantly increase the risk of unreasonable adverse effects. 7 U.S.C. § 136a(c)(3)(B)(i)(I). As discussed in Section I.B, nothing in this provision conflicts with the Copyright Act. Thus, the power to set aside copyright protection in light of the EPA's alleged policy concerns lies not with this Court, but with Congress. *Ruckelshaus*, 467 U.S. at 1018. Indeed, if the EPA were truly concerned about the implications of applying copyright law to pesticide labels, it would have already sought to direct its concern to Congress. Yet, Syngenta has not been able to identify any instances in which the EPA has attempted to address Congress on this issue, and when contacted by Syngenta's counsel, the Justice Department was unable to identify any such instances. (Levine Decl. ¶ 2.)

II. The Merger Doctrine Does Not Preclude Syngenta's Copyright Claims.

The "merger doctrine" polices the boundary between a noncopyrightable idea and a copyrightable expression of that idea. As the Fourth Circuit has explained, "[i]f there is only one way to express the idea," the "'idea' and 'expression' merge and there is no copyrightable material." *M. Kramer Mfg. Co., Inc. v. Andrews*, 783 F.2d 421, 436 (4th Cir. 1986). That is consistent with the weight of authority, including the *ATC* case

[4] The government provides no support for this assertion. As discussed in Section II.C, the EPA has approved a number of me-too labels that differ from the original label.

on which the government relies, which explains that "***when there is essentially only one way to express an idea***, the idea and its expression are inseparable, and the merger doctrine applies. *ATC Distrib. Grp., Inc. v. Whatever It Takes Transmissions & Parts, Inc.*, 402 F.3d 700, 708–09 (6th Cir. 2005) (emphasis added); *accord Soc'y of Holy Transfiguration Monastery, Inc. v. Gregory*, 689 F.3d 29, 53 (1st Cir. 2012); *MyWebGrocer, LLC v. v. Hometown Info, Inc.*, 375 F.3d 190, 194 (2d Cir. 2004). As the court in *FMC* found, the merger doctrine does not apply to pesticide labels because "there are multiple means to express the non-regulated language contained within" pesticide labels. *FMC*, 369 F. Supp. 2d at 567 (citing *Apple Computer, Inc. v. Franklin Computer Corp.*, 714 F.2d 1240, 1253 (3d Cir. 1983)). Thus, the case law does not support the government's assertion that that there must be "hundreds of different ways" of expressing the information on Syngenta's labels (which there are). (SOI at 27.)

Syngenta's labels, which are on the order of 30–50 pages, contain page after page of textual descriptions, tables, and instructions that reflect innumerable choices that the drafters made as to the selection of information to use and recommend from the thousands of studies that Syngenta conducted; the expression of that information including the use of particular word choice, sentence structure, and syntax; and the arrangement of that information in terms of order, organization, and format. (Dkt. 110-13, Clark Decl. ¶¶ 4–5.) The combination and permutations of these specific choices present virtually an infinite number of ways in which the labels could be drafted. Here, Willowood itself revised its labels in response to Syngenta's copyright claims, underscoring that other possible presentations are possible. (Dkts. 110-11, 110-12.) As discussed in Section I.C, the EPA also has previously approved me-too labels containing different label language that was not copied from the language in the original registrant's label, demonstrating that such label language is not limited to "essentially only one way."

The government's attempt to analogize *ATC* only underscores that the merger doctrine is not applicable to Syngenta's labels. Significantly, *ATC* involved the copyrightability of the listing and categorization of ***part numbers*** (such as "45607") in a product catalog. 402 F.3d at 707–10. The court's primary rationale for concluding that the part numbers were not protected by copyright was that they were generated essentially at random and were not creative. *Id.* at 709. Applying the merger doctrine, the court also explained that there was really only one way to express the part numbers:

> For example, the only way to express the prediction that a maximum of four additional types of sealing ring might be developed is to leave four numbers unallocated, and the only way to express the idea that a novel part should be placed with the sealing rings rather than with the gaskets is to place that part with the sealing rings.

Id. at 707. Notably, *ATC* did not address any detailed textual descriptions for the parts themselves that would even be remotely akin to the detailed text in Syngenta's labels. As a comparison, in *MyWebGrocer*, the Second Circuit found that the merger doctrine did not preclude the copyrightability of product descriptions set forth in an online grocery shopping system, even though the product descriptions themselves were taken from third-party product packages. 375 F.3d at 194. As the court explained, "the merger doctrine would not invalidate [a] copyright in the original elements of [the] selection and arrangement" of the product information. *Id.*; *see also Enter. Mgmt. Ltd. v. Warrick*, 717 F.3d 1112 (10th Cir. 2013) (finding merger doctrine inapplicable to a diagram that could be expressed in different ways, such as a pie chart, two-column table, etc.).

Further, although the EPA requires pesticide registrants to submit health and safety data and address such considerations on pesticide labels, the vast majority of Syngenta's labels at issue reflect efficacy claims that the EPA does not require. (Dkt. 110-13, Clark Decl. ¶ 6.) Indeed, pursuant to Congress' 1978 Amendments to FIFRA, the EPA issued a "general waiver of efficacy review" in 1979 and later confirmed in

1996 that (a) it had "stopped evaluating pesticide efficacy for routine label approvals almost two decades ago" and (b) the "EPA's approval of a pesticide label does not reflect any determination on the part of EPA that the pesticide will be efficacious." *Bates v. Dow Agrosciences LLC*, 544 U.S. 431, 440 (2005) (citations omitted). The government counters that the EPA continues to review all aspects of a pesticide label to confirm that it meets FIFRA's safety standard and that it does not include false statements. (SOI at 30.) But the government tacitly acknowledges that neither FIFRA nor the EPA ***requires*** me-too applicants to make any efficacy claims at all, much less the same efficacy claims as the original registrant or express them in a substantially similar manner. Thus, the government cannot plausibly argue that Willowood needed to copy Syngenta's efficacy claims or that there is essentially only one way to express this information.

III. The Government's Implied-License Argument Fails as a Matter of Law.

The government conjures up from whole cloth, and attempts to inject into this case, a brand-new defense of an implied nonexclusive license. As the government acknowledges, however, "an implied nonexclusive license constitutes an affirmative defense." (SOI at 23 (citation omitted).) Here, Willowood's failure to plead an implied-license defense in the first instance "results in a binding waiver of that defense," and the government offers no authority that would allow it to unilaterally raise it at this late stage of the case. *Innovative Legal Mktg., LLC v. Market Masters-Legal*, 852 F. Supp. 2d 688, 694–96 (E.D. Va. 2012) (holding that unpleaded implied-license defense was waived).

Even if it could be properly considered, the government's argument lacks merit. The government cites no case that has found an implied license in this context and essentially tries to shoehorn the circumstances of this case into the three-prong test laid out in *Effects Associates*. (SOI at 24 (citing *Effects Assocs., Inc. v. Cohen*, 908 F.2d 555, 558–59 (9th Cir. 1990).) To the contrary, *SmithKline*, which the government cites

elsewhere and attempts to analogize, explains that an "implied license is [not] clearly a defense in the present circumstances" and "courts have found implied licenses only in 'narrow' circumstances where one party 'created a work at [the other's] request and handed it over, intending that [the other] copy and distribute it." 211 F.3d at 25. Ultimately, the *SmithKline* court did not rule on the implied-license defense, noting that it would require creating new "judge-made" law and that the defense in any event would hinge on the court's finding that Hatch-Waxman required the labels at issue to be copied. *Id.* at 25, n.1. As discussed in Section I.C, FIFRA (unlike Hatch-Waxman) does not require me-too labels to copy label language. For that reason alone, the government's argument fails. Nor can the government show that this case presents the "narrow" circumstance contemplated by the case law, because Syngenta did not create its labels at Willowood's request or hand it over to Willowood intending that it would be copied.

Taken to its logical conclusion, the government's implied-license argument also would lead to absurd results. The government essentially asserts that by virtue of registering azoxystrobin with the EPA, Syngenta impliedly licensed any copyright interest in its labels to future me-too applicants. (SOI at 23–26.) Yet, under that same reasoning, Syngenta would have impliedly licensed *any and all* intellectual property it holds in its azoxystrobin products, from its trademarks and trade dress in its product packaging to its patents on the azoxystrobin compound and manufacturing processes. The government identifies no authority for this proposition. Indeed, even Willowood concedes that at least W-USA infringed Syngenta's patents on the azoxystrobin compound. (Dkt. 105 at 1–2.) Further, as noted in Section I.B, when Congress intended FIFRA to limit intellectual property rights, such as state-law rights in the health and safety data submitted to the EPA, it did so directly and explicitly. Congress, however, has not limited other intellectual property rights, including copyrights and patents.

IV. The Government Simply Repeats Willowood's Fair-Use Arguments, Which Fail as a Matter of Law.

Without presenting any new considerations, the government asserts that Willowood's copying amounts to fair use—a proposition that both *FMC* and *SmithKline* (which the government seeks to analogize) rejected. *FMC*, 369 F. Supp. 2d at 578–80; *SmithKline*, 211 F.3d at 25. In fact, the government suggests that Willowood's copying of Syngenta's labels to sell its own pesticide products is remotely akin to the specific categories of fair use set forth in 17 U.S.C. § 107. Although the government correctly notes that these categories are not exhaustive (SOI 31–32), the law is well established that "the illustrative nature of the categories should not be ignored." *Infinity Broad. Corp. v. Kirkwood*, 150 F.3d 104, 107 (2d Cir. 1998). In fact, as the *SmithKline* court reasoned, fair use is not clearly a defense under these circumstances, because the copying of a product label "is rather different from the sorts of copying traditionally deemed to constitute a fair use, *e.g.*, copying for 'purposes such as criticism, comment, news reporting, teaching . . ., scholarship, or research.'" 211 F.3d at 25 (quoting § 107).

Although the *SmithKline* court did not specifically rule on the fair-use defense, it explained that, like the implied-license defense, it too would require creating new "judge-made" law and in any event would hinge on the court's finding that Hatch-Waxman required the generic labels to be copied. *Id.* at 25, n.1. Similarly, here, the government and Willowood's fair-use argument hinges on their erroneous assumption that FIFRA requires copying. (*See* SOI at 37.) But where *SmithKline* left off, *FMC* completed the analysis with respect to pesticide labels, squarely holding that FIFRA (unlike Hatch-Waxman) does not conflict with the Copyright Act, 369 F. Supp. 2d at 578–71, and that the copying of pesticide labels is not fair use, *id.* at 578–80. Neither the government, nor Willowood, offers any cogent rationale for departing from *FMC*'s holding.

V. This Court Should *Sua Sponte* Grant Summary Judgment in Syngenta's Favor of Copying, Copyrightability, and No Fair Use.

"[D]istrict courts are widely acknowledged to possess the power to enter summary judgments *sua sponte*, so long as the losing party was on notice that she had to come forward with all of her evidence." *Celotex*, 477 U.S. at 326; *see also Hughes v. Bedsole*, 48 F.3d 1376, 1381 (4th Cir. 1995). Here, because Willowood itself moved for summary judgment on Syngenta's copyright claims (Dkts. 87–89), Willowood was on notice that it must come forward with all of its evidence, and summary judgment may be granted in favor of Syngenta. *See Salens v. Tubbs*, 292 F. App'x 438, 441 (6th Cir. 2008).

Specifically, this Court should grant summary judgment in Syngenta's favor that:

(1) Willowood's Azoxy 2SC and AzoxyProp Xtra labels copied Syngenta's QUADRIS® and QUILT XCEL® labels (*see* Section I.D; Dkt. 113 at 12–13);

(2) FIFRA does not preclude Syngenta's copyright claims (*see* Section I.A–D; Dkt. 113 at 25–28);

(3) Syngenta's QUADRIS® and QUILT XCEL® labels comprise copyrightable subject matter (*see* Sections I–II; Dkt. 113 at 22–25); and

(4) Willowood's copying of Syngenta's QUADRIS® and QUILT XCEL® labels does not constitute fair use (*see* Section IV; Dkt. 113 at 28–30).

These issues all arise from Willowood's own Motion for Summary Judgment (Dkts. 87–89), are fully developed in the parties' briefing, do not present any material issues of fact, and are ripe for summary judgment.

CONCLUSION

Syngenta respectfully requests that this Court deny Willowood's Motion for Summary Judgment and grant summary judgment in Syngenta's favor as proposed.

Dated: March 15, 2017

By: */s/ Richard A. Coughlin*

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CERTIFICATE OF SERVICE

The undersigned hereby certifies that the foregoing document has been filed electronically with the Clerk of the Court using the CM/ECF system, which will send notification of such filing to counsel of record in this action.

This the 15th day of March, 2017.

/s/ *Richard A. Coughlin*
Richard A. Coughlin